

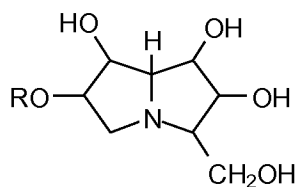
### **Amendments to the claims:**

This listing of claims will replace all prior versions and listings of claims in the application.

### **Listing of Claims:**

1-42 (canceled)

43. (Currently Amended) A method of polarizing an immune response to an antigen in a subject, which method comprises administering to the subject a vaccine comprising one or more antigen(s) and an adjuvant composition comprising a Th1-activating alkaloid in an amount effective to polarize an immune response to the antigen(s) from type 2 towards type 1, wherein the alkaloid has the formula:



wherein R is selected from the group comprising hydrogen, straight or branched, unsubstituted or substituted, saturated or unsaturated acyl, alkyl (e.g. cycloalkyl), alkenyl, alkynyl and aryl groups, or a pharmaceutically acceptable salt or acyl derivative thereof.

44. (Previously Presented) The method of claim 43 wherein the Th1-activating alkaloid stimulates the expression of IL-12 *in vitro* in lymphocytes and/or dendritic cells.

45. (Previously Presented) The method of claim 43 wherein the adjuvant composition further comprises an auxiliary adjuvant.

46. (Previously Presented) The method of claim 44 wherein the adjuvant composition further comprises an auxiliary adjuvant.

47. (Currently Amended) The method of claim 45 wherein the auxiliary adjuvant is selected from:

- (a) a type 2 adjuvant (~~e.g. alum and/or MF59~~); and/or
- (b) a cytokine;
- (c) a depot-forming agent;
- (d) a saponin;
- (e) a submicron oil-in-water emulsion;
- (f) a CpG;
- (g) a lipid A derivative;
- (h) an MDP;
- (i) an ISCOM®;
- (j) an antigen-presenting cell (APC) (for example, a dendritic cell);
- (k) a cytotoxic T lymphocyte (CTL); and
- (l) a synergistic combination of any of the above.

48. (Currently Amended) The method of claim 46 wherein the auxiliary adjuvant is selected from:

- (m) a type 2 adjuvant (~~e.g. alum and/or MF59~~); and/or
  - (n) a cytokine;
  - (o) a depot-forming agent;
  - (p) a saponin;
  - (q) a submicron oil-in-water emulsion;
  - (r) a CpG;
  - (s) a lipid A derivative;
  - (t) an MDP;
  - (u) an ISCOM®;
  - (v) an antigen-presenting cell (APC) (for example, a dendritic cell);
  - (w) a cytotoxic T lymphocyte (CTL); and
- a synergistic combination of any of the above.

49. (Previously Presented) The method of claim 43 wherein the vaccine is selected from: (a) a subunit vaccine; (b) a conjugate vaccine; (c) a DNA vaccine; (d) a recombinant vaccine; (e) a mucosal vaccine; (f) a therapeutic vaccine; (g) a prophylactic vaccine.

50. (Previously Presented) The method of claim 48 wherein the vaccine is selected from: (a) a subunit vaccine; (b) a conjugate vaccine; (c) a DNA vaccine; (d) a recombinant vaccine; (e) a mucosal vaccine; (f) a therapeutic vaccine; (g) a prophylactic vaccine.

51. (Currently Amended) The method of claim 43 wherein the one or more antigen(s) are selected from:

- (a) nucleic acid(s) which encode one or more antigenic protein(s);
- (b) protein(s) or peptide(s);
- (c) glycoprotein(s);
- (d) polysaccharide(s) (e.g. carbohydrate(s));
- (e) fusion protein(s);
- (f) lipid(s);
- (g) glycolipid(s);
- (h) peptide mimic(s) of polysaccharides;
- (i) carbohydrate(s) and a protein(s) in admixture;
- (j) carbohydrate-protein conjugate(s);
- (k) cells or extracts thereof;
- (l) dead or attenuated cells, or extracts thereof;
- (m) tumour cells or extracts thereof;
- (n) viral particles ~~(e.g. attenuated viral particles or viral components)~~;
- (o) allergen(s);
- (p) mixtures of any of (a) to (o).

52. (Currently Amended) The method of claim 50 wherein the one or more antigen(s) are selected from:

- (q) nucleic acid(s) which encode one or more antigenic protein(s);
- (r) protein(s) or peptide(s);

- (s) glycoprotein(s);
- (t) polysaccharide(s) (e.g. carbohydrate(s));
- (u) fusion protein(s);
- (v) lipid(s);
- (w) glycolipid(s);
- (x) peptide mimic(s) of polysaccharides;
- (y) carbohydrate(s) and a protein(s) in admixture;
- (z) carbohydrate-protein conjugate(s);
- (aa) cells or extracts thereof;
- (bb) dead or attenuated cells, or extracts thereof;
- (cc) tumour cells or extracts thereof;
- (dd) viral particles (~~e.g. attenuated viral particles or viral components~~);
- (ee) allergen(s);
- (ff) mixtures of any of (a) to (o).

53. (Previously Presented) The method of claim 51 wherein the one or more antigen(s) comprise a bacterial antigen, a viral antigen, a fungal antigen, a protozoal antigen, a prion antigen, a neoantigen, a tumour-associated antigen or a self-antigen.

54. (Previously Presented) The method of claim 52 wherein the one or more antigen(s) comprise a bacterial antigen, a viral antigen, a fungal antigen, a protozoal antigen, a prion antigen, a neoantigen, a tumour-associated antigen or a self-antigen.

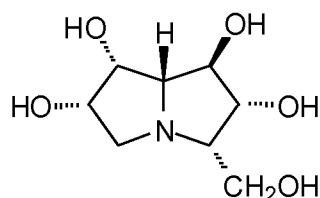
55. (Previously Presented) The method of claim 51 wherein the one or more antigen(s) are dose-spared.

56. (Previously Presented) The method of claim 54 wherein the one or more antigen(s) are dose-spared.

57. (Previously Presented) The method of claim 43 wherein the vaccine is administered orally, mucosally, topically, epicutaneously, intramuscularly, intradermally, subcutaneously, intranasally, intravaginally, sublingually or *via* inhalation.

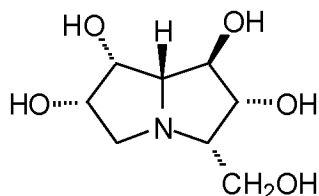
58. (Previously Presented) The method of claim 56 wherein the vaccine is administered orally, mucosally, topically, epicutaneously, intramuscularly, intradermally, subcutaneously, intranasally, intravaginally, sublingually or *via* inhalation.

59. (Currently Amended) The method of claim 43 wherein the Th-1 activating alkaloid is 3,7-diepicasuarine has the formula:



or a pharmaceutically acceptable salt or acyl derivative thereof.

60. (Currently Amended) The method of claim 58 wherein the Th-1 activating alkaloid is 3,7-diepicasuarine has the formula:



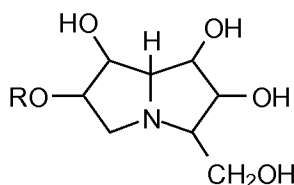
or a pharmaceutically acceptable salt or acyl derivative thereof.

61. (Currently Amended) A method of polarizing an immune response to an antigen in a subject, which method comprises administering to the subject a vaccine comprising one or more antigen(s) and an adjuvant composition comprising a Th1-activating alkaloid in an amount

effective to polarize an immune response to the antigen(s) from type 2 towards type 1, wherein the alkaloid is selected from the following classes:

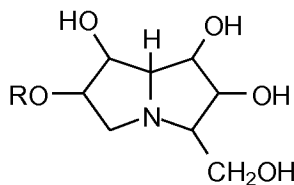
- (a) piperidines alkaloids;
- (b) pyrroline alkaloids;
- (c) pyrrolidines alkaloids;
- (d) pyrrolizidine alkaloids;
- (e) indolizidine alkaloids;
- (f) nortropane alkaloids;

wherein the alkaloid has the formula:



wherein R is selected from the group comprising hydrogen, straight or branched, unsubstituted or substituted, saturated or unsaturated acyl, alkyl (e.g. cycloalkyl), alkenyl, alkynyl and aryl groups, or a pharmaceutically acceptable salt or an acyl derivative thereof.

62. (Currently Amended) A method of polarizing an immune response to an antigen in a subject, which method comprises administering to the subject a vaccine comprising one or more antigen(s) and an adjuvant composition comprising a Th1-activating alkaloid in an amount effective to polarize an immune response to the antigen(s) from type 2 towards type 1, wherein the alkaloid is a pyrrolizidine alkaloid, and wherein the alkaloid has the formula:



wherein R is selected from the group comprising hydrogen, straight or branched, unsubstituted or substituted, saturated or unsaturated acyl, alkyl (e.g. cycloalkyl), alkenyl, alkynyl and aryl groups, or a pharmaceutically acceptable salt or an acyl derivative thereof.